REMARKS/ARGUMENTS

Claims 1-7, 9-17, 19, and 21-26 are pending in the present application.

This Amendment is in response to the Final Office Action mailed October 5, 2009 to support a Request for Continued Examination (RCE) filed concurrently. In the Final Office Action, the Examiner objected to the drawings, rejected claims 1, 2, 9, 19, 23, and 26 under 35 U.S.C. §102(a/e); claim 11 under 35 U.S.C. §102(b); and claims 3-7, 10, 12-17, 21, 24, and 25 under 35 U.S.C. §103(a). Applicant has amended the Specification and claims 1, 9, 11, 12, 14, 23, and 26. Reconsideration in light of the amendments and remarks made herein is respectfully requested.

Objections to the Drawings

In the Office Action, the Examiner objected to the drawings under 37 C.F.R §1.83(a). Specifically, the Examiner contends that the "Fresnel lens", "multiplexing circuit", and "sterilization mechanism" as cited in the clams must be shown or the feature(s) cancelled from the claim(s). In response, Applicant has amended claim 12 and the Specification.

Regarding the "Fresnel lens", Application respectfully disagrees with the Examiner. 37 C.F.R §1.83(a) specifically states:

> (a) The drawing in a nonprovisional application must show every feature of the invention specified in the claims. However, **conventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation** (*e.g.*, a labeled rectangular box). In addition, tables and sequence listings that are included in the specification are, except for applications filed under 37 U.S.C. 371, not permitted to be included in the drawings. (Emphasis added.)

The Fresnel lens is shown as element "140" in Figure 1. The Fresnel lens is a conventional feature that is disclosed in the description (Specification, page 7, lines 14-16). It is noted that aspect of the Fresnel lens is recited in dependent claims, and provides further specificity to the independent claims and has fully supported in the specification. Accordingly, Applicant respectfully requests the objections to the drawings be withdrawn.

Rejection Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1, 2, 9, 19, 23, and 26 under 35 U.S.C. §102(a/e) as being anticipated by U.S. Patent No. 6,601,581 issued to Babaev ("Babaev"); and claim 11 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,823,428 issued to Humberstone ("Humberstone"). Applicant respectfully traverses the rejection and submits that the Examiner has not met the burden of establishing a prima facie case of anticipation.

1. Claims 1, 2, 9, 19, 23, and 26:

Babaev discloses a method and device for ultrasound drug delivery. A liquid or powder drug is delivered to a radiation surface of a piezofilm/disk or ultrasonic transducer tip such that the liquid is dropped to the radiation surface under gravity (Babaev, col. 4, lines 1-4). The radiation surface of the piezofilm/disk or ultrasonic transducer must be placed at some angle with relation the horizontal (Babaev, col. 4, lines 5-6). A liquid (drug) drop or flow 10 falls under gravity to a radiation surface 13 of piezofilm/disk 15 via dispenser tube 12. Drop 10 contacts surface 13 at point 14 and creates directed aerosol 16. Radiation surface 13 of piezofilm/disk 15 is placed at an angle θ with respect to the horizontal (Babaev, col. 4, lines 55-57).

Babaev does not disclose, either expressly or inherently, at least one of: (1a) a first driver element to generate acoustic energy, the first driver element generating acoustic energy in pulses that are of a short duration and low frequency such that a droplet of pharmaceutical product is output from a capillary wave; (2a) a first acoustic lens positioned between the first driver element and the capillary wave to focus the acoustic energy generated by the first driver element; and (3a) a delivery system to maintain the pharmaceutical product in a position to receive the acoustic energy from the first acoustic lens and cause ejection of the droplet of pharmaceutical product, as recited in claim 1; or (1b) a driver element to generate acoustic energy, the driver element designed to generate acoustic energy in pulses that are of a short duration and low frequency such that a plurality of droplets of pharmaceutical product is output from a capillary wave wherein the driver element is programmed to output acoustic energy at a frequency below 15 MHz; (2b) an acoustic lens positioned between the first driver element and the capillary wave to focus the acoustic energy generated by the driver element; and (3b) a delivery system to maintain the pharmaceutical product in a position to receive the acoustic energy from the acoustic lens and cause ejection of the droplets of pharmaceutical product, as recited in claim 9;

or (1c) generating a pulse of acoustic energy, the pulse having a short duration and low frequency such that the pulse of acoustic energy generates capillary waves, at least one capillary wave ejecting at least one droplet of pharmaceutical product; (2c) focusing the acoustic energy between the pulse of acoustic energy and the capillary waves; and, (3c) positioning the droplet near a human orifice for inhalation into a respiratory system, as recited in claim 23; or (1d) a pharmaceutical product; (2d) a driver element to generate acoustic energy, the driver element generating acoustic energy in pulses that are of a short duration and low frequency such that a droplet of the pharmaceutical product is output from a capillary wave; (3d) an acoustic lens positioned between the first driver element and the capillary wave to focus the acoustic energy generated by the driver element; and (4d) a delivery system to maintain the pharmaceutical product in a position to receive the acoustic energy from the acoustic lens and cause ejection of the droplet of the pharmaceutical product, as recited in claim 26.

Babaev merely discloses a liquid (drug) drop or flow 10 falls under gravity to a radiation surface 13 of piezofilm/disk 15 via dispenser tube 12 (Babaev, col. 4, lines 55-57), NOT a delivery system to receive the acoustic energy and cause ejection of the droplet of pharmaceutical product from the first acoustic lens. The dispenser tube 12 allows the liquid drop to fall under gravity. The drop is not ejected by the acoustic energy.

In addition, Babaev merely discloses a radiation surface 13 (Babaev, col. 4, lines 55-57), NOT an acoustic lens to focus the acoustic energy generated by the first driver element. In the Final Office Action, the Examiner contends that Babaev discloses the surface 13 as the acoustic lens, citing col. 4, lines 55-56 (Final Office Action, page 3, paragraph 5; page 9, paragraph 30). Applicant respectfully disagrees. For ease of reference, the cited excerpt is copied below.

> "FIG. 1 depicts a basic concept of the ultrasonic aerosol drug delivery method and device according to the invention. *A liquid (drug) drop or flow 10 falls under gravity to a radiation surface 13 of piezofilm/disk 15* via dispenser tube 12. Drop 10 contacts surface 13 at point 14 and creates directed aerosol 16. *Radiation surface 13 of piezofilm/disk 15 is placed at an angle θ with respect to the horizontal*." (Babaev, col. 4, lines 51-57. *Emphasis added.*)

As seen from the above excerpt, the radiation surface 13 is merely a surface of an piezofilm/disk 15. It is placed at an angle θ with respect to the horizontal (Babaev, col. 4, lines

55-57). Accordingly, it cannot be an acoustic lens to focus the acoustic energy generated by the first driver element.

Furthermore, the radiation surface 13 is not placed between the driver element and the capillary wave. It is merely a surface to receive the directed aerosol 16. To clarify this aspect of the invention, claims 1, 9, 11, 14, 23, and 26 have been amended.

In addition, Babaev merely discloses the liquid drop to be released from a dispenser tube 12 (Babaev, col. 4, lines 55-57), NOT output from a capillary wave. Babaev was well aware of capillary waves (Babaev, col. 1, lines 25-28), but chose to use a dispenser and gravity to output the liquid drop. This indicated that it was not obvious to Babaev to use capillary waves and effectively teaches away from the claimed invention.

2. Claim 11:

Humberstone discloses a liquid spray apparatus and method. A circuit 8 vibrates a perforate membrane 5 substantially perpendicular to the plane of the membrane, so producing droplets of liquid emerging away from the front face 51 of the perforate membrane (Humberstone, col. 5, lines 13-17). Each perforation 50 has openings 53 in the front exit face and openings 54 in the rear entry face (Humberstone, col. 5, lines 30-32).

Humberstone does not disclose, either expressly or inherently, at least one of: (1e) a portable energy supply; (2e) at least one transducer coupled to the portable energy supply, the at least one transducer to output acoustic energy below 15 Mhz and generate a capillary wave; (3e) a plurality of lenses to receive and focus energy from the at least one transducer; and (4e) a delivery system to maintain a reservoir of pharmaceutical product, a distance from a top surface of a lens and a surface of the reservoir of pharmaceutical product being less than 150 micro meters, the reservoir of pharmaceutical product to receive energy from the plurality of lenses the received energy to cause ejection of a plurality of droplets.

Humberstone merely discloses a perforate membrane 5 to produce droplets of liquid from a circuit 8 (Humberstone, col. 5, lines 13-17), NOT one transducer to generate a capillary wave and a delivery system to cause ejection of a plurality of droplets. The vibration of membrane 5 excites capillary waves in the surface of the liquid meniscus 67 (Humberstone, Figure 6d, col. 7, lines 17-20).

In addition, Humberstone merely discloses an openings 53 in the front exit face and openings 54 in the rear entry face of the membrane 5 (Humberstone, col. 5, lines 30-32), NOT a plurality of lenses to receive and focus energy from the at least one transducer. An opening is a hole or a gap. It cannot be a lens.

Moreover, Humberstone merely discloses the membrane 5 is placed next to the piezoelectric ceramic annuls 72 (Humberstone, col. 5, lines 56-61; Fig. 4b), NOT positioned between the driver element and the capillary wave. Accordingly, it cannot focuses the acoustic energy. To clarify this aspect of the invention, claim 11 has been amended.

To anticipate a claim, the reference must teach every element of a claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Vergegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). The Examiner bears the burden of presenting at least a prima facie case of anticipation. *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 138-139 (Fed. Cir. 1986); *In re Wilder*, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970). Only if that burden is met, does the burden of going forward shift to the applicant. *In re King*, 801 F.2d at 1327, 231 USPQ at 138-139; *In re Wilder*, 429 F.2d at 450, 166 USPQ at 548. Once a prima facie case is established and rebuttal evidence is submitted, the ultimate question becomes whether, based on the totality of the record, the Examiner carried his burden of proof by a preponderance. See *In re Oetiker*, 977 F.2d 1443, 1445. 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). If the Examiner fails to establish a prima facie case, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Since the Examiner failed to show that Babev or Humberstone teaches or discloses any one of the above elements, the rejection under 35 U.S.C. §102 is improper.

Therefore, Applicant believes that independent claims 1, 9, 11, 23, and 26 and their respective dependent claims are distinguishable over the cited prior art references. Accordingly, Applicant respectfully requests the rejection under 35 U.S.C. §102(a/b/e) be withdrawn.

Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 10 under 35 U.S.C. §103(a) as being unpatentable over Babaev; claims 3-6, 14-16, and 22 under 35 U.S.C. §103(a) as being unpatentable over Babev in view of U.S. Patent No. 5,339,101 issued to Rawson ("Rawson"); claims 6 and 7 under 35 U.S.C. §103(a) as being unpatentable over Babev in view of U.S. Patent No. 5,231,426 issued to Sweet ("Sweet"); claim 13 under 35 U.S.C. §103(a) as being unpatentable over Babev in view of U.S. Patent No. 6,012,454 issued to Hodson ("Hodson"); claims 21, 24, and 25 under 35 U.S.C. §103(a) as being unpatentable over Babev in view of Elrod ("Elrod") "Nozzless droplet formation with focused acoustic beams"; claim 17 under 35 U.S.C. §103(a) as being unpatentable over Babev in view of Rawson as applied to claim 14 above, and further in view of U.S. Patent No. 6,205,999 issued to Ivri ("Ivri"); and claim 12 under 35 U.S.C. §103(a) as being unpatentable over Humberstone in view of U.S. Patent No. 5,372,126 issued to Blau ("Blau").

Applicant respectfully traverses the rejection and submits that the Examiner has not met the burden of establishing a prima facie case of obviousness.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *MPEP §2143, p. 2100-126 to 2100-130 (8th Ed., Rev. 5, August 2006).* Applicant respectfully submits that there is no suggestion or motivation to combine their teachings, and thus no *prima facie* case of obviousness has been established.

Furthermore, the Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated: "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined." MPEP 2141. In *KSR International Co. vs. Teleflex, Inc.*, 127 S.Ct. 1727 (2007) (Kennedy, J.), the Court explained that "[o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands

known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." The Court further required that an explicit analysis for this reason must be made. "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR 127 S.Ct.* at 1741, quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). In the instant case, Applicant respectfully submits that there are significant differences between the cited references and the claimed invention and there is no apparent reason to combine the known elements in the manner as claimed, and thus no *prima facie* case of obviousness has been established.

1. Claim 10:

Babaev is discussed above.

The Examiner contends that Babaev discloses a range of droplet diameters to be 0.1 μ to several millimeters, citing Babaev, col. 1, lines 57-60. However, the cited excerpt merely discusses the disadvantages of non-uniformity of the particle size, not what is produced by Babaev technique. In addition, Babaev technique can only produce a droplet size of 0.5 mm, or down to 50 μ with difficulties as below.

> "The distance between the radiation surface of the transducer or piezofilm/disk and the liquid tube will preferably be about the size of liquid drop diameter ~ 0.5 mm and above. Distances of less than 0.5 mm (up to 50 micron) can be used as well; however, this may cause some assembly difficulties" (Babaev, col. 4, lines 42-47)

As seen from the above excerpt, and since Babaev was well aware of the particle size of 0.1 μ to several millimeters (Babaev, col. 1, lines 57-60), but could not produce droplet size of less than 50 μ, Babaev effectively teaches away from the claimed invention.

2. Claims 3-6, 14-16, and 22:

Babaev is discussed above.

Rawson discloses an acoustic ink printhead. One or more thin Ti-Au layers 11 are provided on the top of the substrate 10, to serve as lower electrodes for the transducers (Rawson,

col. 2, lines 51-53). Fresnel lenses 15 are etched in the top of the dielectric layer above each of the piezoelectric transducers (Rawson, col. 2, lines 67-68).

As discussed above, Babaev does not disclose at least one of the elements (1a) – (3a) as recited in claim 1. Accordingly, a combination of Babaev with any other references in rejecting claims 3-6, 14-16, and 22, is improper.

Babaev and Rawson, taken alone or in combination, do not disclose or render obvious, at least one of: (1f) a portable energy supply; (2f) at least one transducer coupled to the portable energy supply, the at least one transducer to output acoustic energy below 15 Mhz and generate a capillary wave; (3f) a plurality of lenses to receive and focus energy from the at least one transducer; and (4f) a delivery system to maintain a reservoir of pharmaceutical product, a distance from a top surface of a lens and a surface of the reservoir of pharmaceutical product ~~is~~ being less than 150 micro meters, the reservoir of pharmaceutical product to receive energy from the plurality of lenses the received energy to cause ejection of a plurality of droplets, as recited in claim 14.

Furthermore, modifying Babaev to incorporate the teachings of Rawson would render the Babaev technique being modified unsatisfactory for its intended purpose, or change its principle of operation. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). If the proposed modification or combination of the prior art would change the principle of operation of the prior invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Here, modifying Babaev to incorporate the Rawson Fresnel lenses would render the Babaev technique unworkable because Babaev does not disclose or render obvious an acoustic lens. Replacing the radiation surface 13 (Babaev, col. 4, lines 55-57) by a plurality of Fresnel lenses would not allow the lenses to focus the acoustic energy. Accordingly, there is no suggestion or motivation to make the proposed modification.

Moreover, Rawson does not disclose or render obvious plastic lenses, as recited in claim 4 and 16; and one droplet diameter is less than 5 micrometers as recited in claim 22. The Examiner merely concludes that the modification of Babaev by Rawson discloses the claimed

limitations without providing analysis on how these modification can be achieved (Final Office Action, page 6, paragraphs 16 and 17).

3. Claims 6 and 7:

Babaev is discussed above.

Sweet discloses a nozzleness droplet projection system. Electronic power supply 21 is connected to the array of electro-acoustic transducers 15 through an electronic multiplexer 41 which selectively excites any sequence of electro-acoustic transducers 15 to project a desired pattern of droplets 12 onto the projection surface 14 (Sweet, col. 3, lines 45-50).

As discussed above, Babaev does not disclose at least one of the elements (1a) – (3a) as recited in claim 1. Accordingly, a combination of Babaev with any other references in rejecting claims 6 and 7, which depend on claim 1, is improper.

Furthermore, Sweet merely discloses an electronic multiplexer 41 which selectively excites any sequence of electro-acoustic transducers 15 (Sweet, col. 3, lines 45-50), not a multiplexing circuit that directs RF energy from the portable energy source to alternately switch groups of the ejectors on and off, as recited in amended claim 7. Selectively exciting a sequence of transducers is not the same as alternately switching on and off the ejectors. To clarify this aspect of the invention, claims 6 and 7 have been amended.

4. Claim 13:

Babaev is discussed above.

Hodson discloses a dry powder inhalation device. An inhaler has a housing comprising a body portion (45) and a cover (47) pivotally mounted at (49) movable between a closed format (Hodson, col. 15, lines 44-50).

As discussed above, Babaev does not disclose at least one of the elements (1a) – (3a) as recited in claim 1. Accordingly, a combination of Babaev with any other references in rejecting claim 13, which depends on claim 1, is improper.

Furthermore, Hodson merely discloses a cover (47) pivotally mounted at (49) movable between a closed format (Hodson, col. 15, lines 44-50), NOT a MEMS cover. As the Examiner may be aware, Micro-Electro-Mechanical Systems (MEMS) is the integration of mechanical elements, sensors, actuators, and electronics on a common silicon substrate through

microfabrication technology. The Examiner has not shown that the cover in Hodson is fabricated using the MEMS technology.

5. Claims 21, 24, and 25:

Babaev is discussed above.

Elrod discloses a nozzleless droplet formation with focused acoustic beams. Following the burst of acoustic energy, a mound rises up from the liquid surface, and a single droplet is expelled at a velocity of several meters per second. After droplet ejection, the surface relaxes and a capillary wave propagates away from the focal spot (Elrod, page 3441, left column, second paragraph)

As discussed above, Babaev does not disclose at least one of the elements (1a) – (3a) as recited in claim 1, and (1c) – (2c) as recited in claim 23. Accordingly, a combination of Babaev with any other references in rejecting claim 21, which depends on claim 1, or claims 24-25, which depend on claim 23, is improper.

6. Claim 17:

Babaev and Rawson are discussed above.

Ivri discloses methods and apparatus for storing chemical compounds in a portable inhaler. An apparatus 10 includes an inhalation flow sensor 24 which detects the inhalation flow produced by the patient when inhaling from mouthpiece 22 (Ivri, col. 7, lines 50-53). Upon detection of the inhalation, sensor 24 sends an electrical signal to an electronic circuit which in turn sends an alternating voltage to vibrate a piezoelectric member 26 of aerosol generator 22 to aerosolize a liquid (Ivri, col. 7, lines 53-56).

As discussed above, Babaev and Rawson do not disclose at least one of the elements (1f) – (4f) as recited in claim 14. Accordingly, a combination of Babaev with any other references in rejecting claim 17, which depends on claim 14, is improper.

Furthermore, Ivri merely discloses an inhalation flow sensor 24 which detects the inhalation flow (Ivri, col. 7, lines 50-53), not a circuit that detects a flow of air when a critical air speed is reached, as recited in claim 17. Detecting the inhalation flow merely detects if there is a flow. It does not detect the airflow when a critical air speed is reached.

7. Claim12:

Humberstone is discussed above.

Blau discloses a pulmonary sampling chamber. Ultraviolet light fixtures are place in the sputum induction (SI) room in a manner to sterilize the air and kill aerosolized microorganisms (Blau, col. 1, lines 48-50).

As discussed above, Humberstone does not disclose at least one of the elements (1e) – (4e) as recited in claim 11. Accordingly, a combination of Humberstone with any other references in rejecting claim 12, which depends on claim 11, is improper.

Furthermore, Blau merely discloses using the UV light to sterilize the air kill aerosolized microorganisms (Blau, col. 1, lines 48-50), NOT an ultraviolet source to sterilize the ejector head. Sterilizing the air does not sterilize the ejector head or the acoustic lens. To clarify this aspect of the invention, claim 12 has been amended.

The Examiner failed to establish a prima facie case of obviousness and failed to show there is teaching, suggestion, or motivation to combine the references. When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to: (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. *Hodosh v. Block Drug Col, Inc.,* 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986). "When determining the patentability of a claimed invention which combined two known elements, 'the question is whether there is something in the prior art as a whole suggest the desirability, and thus the obviousness, of making the combination.'" *In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992), 24 USPQ2d 1040; *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462, 221 USPQ (BNA) 481, 488 (Fed. Cir. 1984). To defeat patentability based on obviousness, the suggestion to make the new product having the claimed characteristics must come from the prior art, not from the hindsight knowledge of the invention. *Interconnect Planning Corp. v. Feil*, 744 F.2d 1132, 1143, 227 USPQ (BNA) 543, 551 (Fed. Cir. 1985). To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the Examiner to show a motivation to combine the references that create the case of obviousness. In other words, the Examiner must show reasons that a skilled artisan, confronted with the same problems as the inventor and with no

knowledge of the claimed invention, would select the prior elements from the cited prior references for combination in the manner claimed. *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1996), 47 USPQ 2d (BNA) 1453. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or implicitly suggest the claimed invention or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973. (Bd.Pat.App.&Inter. 1985). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Furthermore, although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." *In re Mills*, 916 F.2d at 682, 16 USPQ2d at 1432; *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992), 23 USPQ2d 1780.

Moreover, the Examiner failed to establish the factual inquires in the three-pronged test as required by the *Graham* factual inquires. There are significant differences between the cited references and the claimed invention as discussed above. Furthermore, the Examiner has not made an explicit analysis on the apparent reason to combine the known elements in the fashion in the claimed invention. Accordingly, there is no apparent reason to combine the teachings of Babaev, Humbersone, Rawson, Sweet, Hodson, Elrod, Ivri, and Blau in any combination.

In the present invention, the cited references do not expressly or implicitly disclose any of the above elements. In addition, the Examiner failed to present a convincing line of reasoning as to why a combination of Babaev, Humbersone, Rawson, Sweet, Hodson, Elrod, Ivri, and Blau is an obvious application of inhaler using focused acoustic waves or an explicit analysis on the apparent reason to combine Babaev, Humbersone, Rawson, Sweet, Hodson, Elrod, Ivri, and Blau in the manner as claimed.

Therefore, Applicant believes that independent claims 1, 9, 11, 14, 23, and 26 and their respective dependent claims are distinguishable over the cited prior art references. Accordingly, Applicant respectfully requests the rejection under 35 U.S.C. §103(a) be withdrawn.

Conclusion

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

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By / THINH V. NGUYEN /
Thinh V. Nguyen
Reg. No. 42,034
Tel.: (714) 557-3800 (Pacific Coast)

1279 Oakmead Parkway
Sunnyvale, CA 94085-4040